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(54) METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS

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- (52) **U.S. Cl.** **514/629**; 564/123; 564/308; 564/427; 568/306

(56) References Cited

OTHER PUBLICATIONS

Concomitant_drugs (wikidpedia document).*

Morris et al. BMJ vol. 327, 2003, p. 1275-76.*

Caraco, et al; "Acute Colchicine Intoxication—Possible Role of Erythromycin Administration"; Journal of Rheumatology; 19; pp. 494-496; (1992).

Horn, et al.; "Life-Threatening Colchicine Drug Interactions"; Pharmacy Times; p. 111; (May 2006).

Perez-Ruiz, et al., "Optimisation of the Treatment of Acute Gout"; BioDrugs; 13; pp. 415-423; (2000).

Rollot, et al., "Acute Colchicine Intoxication During Clarithromycin Administration"; The Annals of Pharmacotherapy; 38; pp. 2074-2077; (2004).

Terkeltaub, Robert A.; "Gout"; Tne New England Journal of Medicine; 349; pp. 1647-1655; (2003).

Van Der Velden, et al.; "Colchicine-Induced Neuromyopathy in a Patient with Chronic Renal Failure: The Role of Clarithromycin"; Netherlands Journal of Medicine; 66; pp. 204-206; (2008).

Waknine, Yael; "FDA Safety Changes: Dexedrine and Biaxin CME/CE"; Medscape Medical News; http://bcbsma.medscape.com/viewarticle/54411; 5 pages; (2006).

Terkeltaub, et al.; "Comparison of Low-Dose vs High-Dose Oral Colchicine Regimens in Patients with Gout Flares"; Presentation at the American College of Rheumatology Scientific Meeting; San Francisco, CA; Oct. 24-29, 2008.

Terkeltaub, et al.; "The Clinical Relevance of P-gp and CYP 3A4 on Colchicine Metabolism and Elimination"; Presentation at the American College of Rheumatology Scientific Meeting; San Francisco, CA; Oct. 24-29, 2008.

Brooks; "Rheumatic Disorders" chapter 25 of Avery's Drug Therapy, pub. 1997 by Adis International, pp. 1113-1161.

Hung et al.; "Fatal Interaction Between Clarithromycin And Colchicines In Patients With Renal Insufficiency: A Retrospective Study"; Clarithromycin And Colchicine Interaction; 41; pp. 291-300 (2005).

Krishnan, et al.; "Gout in Ambulatory Care Settings in the United States"; Juornal of Rheumatology; 35; pp. 498-501; (2008).

Clarithromycin Tablets, USP; Clarithromycin for Oral Suspension, USP, BIAXIN XL Filmtab; Abbott Laboratories; 07E-010-U780-4 Master; 26 pages; Reference 03-5569-R3 Revised Mar. 2007.

U.S. Appl. No. 12/368,700 Non-final Office Action dated Apr. 27, 2009, 77 pages.

Leiken et al., "Colchicine"; Poisoning and Toxicology Handbook (4th Ed.), Aug. 2007, p. 216.

* cited by examiner

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(57) ABSTRACT

Methods for concomitant administration of colchicine together with one or more macrolide antibiotics, e.g., clarithromycin or erythromycin, are disclosed. Such methods reduce the dangers commonly associated with such concomitant administration and provide additional benefits. Methods of notifying health care practitioners and patients regarding appropriate dosing for co-administration of colchicine together with macrolide antibiotics are also provided.

8 Claims, 2 Drawing Sheets